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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/825,930

04/16/2004

Robert S. Neuwirth

ABL-101

9014

7590

07/24/2006

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EXAMINER

ARNOLD, ERNST V

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 07/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/825,930		NEUWIRTH, ROBERT S.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Ernst V. Arnold		1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9, 11-30 and 37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-13, 24-26, 28-30 and 37 is/are rejected.
- 7) ☒ Claim(s) 14-23 and 27 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/29/06</u> .   | 6) <input type="checkbox"/> Other: ____                                     |

### **DETAILED ACTION**

The Examiner acknowledges receipt of Applicant's remarks filed on 4/21/06. The Examiner has fully considered Applicant's remarks. Applicant has cancelled claims 10 and 31-36. Claims 1-9, 10-30 and 37 are pending in the application.

#### **Withdrawn rejections/objections:**

1. Claims 10 and 11 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant has cancelled claim 10 and deleted substantially from claim 11. The Examiner withdraws the rejection.

2. Claims 1, 2, 8, 9, 12, 16-18, 24, 25, 28, 30 and 37 were rejected under 35 U.S.C. 102(b) as being anticipated by Kodama et al. (JP 6-172585) and claims 1, 12, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kodama et al. (JP 06172585A). Applicant amended claim 1 to recite a size limitation of beads having an average diameter in the range of about 1 to about 6 millimeters. Kodama et al. do not disclose this exact size and the Examiner withdraws the rejections.

3. Claims 1-3, 6, 8, 12, 13, 24-27 and 37 were rejected under 35 U.S.C. 102(b) as being anticipated by Siiman et al. (US 5,552,086). Applicant amended claim 1 to recite a size limitation of beads having an average diameter in the range of about 1 to about 6 millimeters. Siiman et al. do not disclose this exact size and the Examiner withdraws the rejection.

4. Claims 1, 10, 11 and 19-23 were rejected under 35 U.S.C. 103(a) as being unpatentable over Hirai et al. (US 5,213,895) in view of Block (Disinfection, Sterilization and Preservation 1977, pages 395-407). Applicant asserted that one of ordinary skill in the art would not have been motivated to combine the references because the references are directed to entirely different fields (catalysts and fields of electric and magnetic materials versus disinfectants) and The Examiner finds this argument persuasive and withdraws the rejection.

**Maintained rejections:**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6, 8, 10, 11-13, 24, 25, 26, 28, 30 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsukisaka et al. (JP 05345010A).

The English language Abstract DERWENT-ACC-NO: 1994-039723 abstracting JP 05345010A and the machine translation have been provided for Applicant's benefit. The Abstract discloses a porous antibiotic bead with binder. The porous antibiotic bead with binder can be used in sanitary goods, which the Examiner interprets to mean that the beads are suitable for physiological use ([0001]). The bead can contain a water-soluble salt of an antibiotic metal (silver), such as silver nitrate (a water soluble inorganic salt) thus reading on instant claims 1, 2, 12 and 13 ([0013] and [0014]).

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Styrene beads and polyethylene beads can be used (instant claims 3, 6 and 37). The Examiner interprets perforated polystyrene beads of instant claim 6 to mean porous. The metal is present from 0.01-10 w/w% and the average particle size might be 0.1-10 mm (5 mm is disclosed) and bead size can be easily regulated thus reading on instant claims 10 and 11 (Abstract and [0045]). The binder is distributed on the surface of the bead and represented physiologically tolerable alginic acid, carboxymethyl cellulose (CMC), polystyrene sulphonate, polyacrylate, etc..., thus reading on instant claims 24-26, 28 and 30.

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

With respect to the tissue necrosing amount of a water soluble silver ion releasing compound, the Examiner does not have the capacity to test the composition of the Abstract to observe whether or not it will necrose tissue. When the compositions between the prior art and the instantly claimed invention appear to be the same then the burden is placed on the Applicant to demonstrate otherwise.

**Response to arguments:**

Applicant asserted that Tsukisaka et al. teach a composite bead in which the metal salt is intimately mixed with the binder and a powdered support material to form the bead. Applicant asserted that the composite materials of Tsukisaka et al. are not suitable for treatment of menorrhagia. The Examiner respectfully disagrees with this opinion. Tsukisaka et al. clearly point out polystyrene beads in the Abstract. Tsukisaka et al. clearly demonstrate forming beads of 5 mm ([0045]). Tsukisaka et al. clearly teach silver nitrate as an antibacterial metal ([0013] and [0014]). It is the Examiner's position that any amount of antibacterial metal located on the surface of the bead would serve to coat the bead to some degree. The intended use of the beads is not further limiting as explained in the prior office action.

***Claim Rejections - 35 USC § 102***

Claims 1-3, 6, 8, 9, 12, 13, 24, 25, 28-30 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Hirai et al. (US 5,213,895).

Hirai et al. disclose a particle-bearing composite comprising a solid carrier and polymer-protected particles adsorbed thereon (Abstract and column 5, lines 58-62). The solid carrier is preferable porous and made from organic polymers such as polystyrene and have a size of from about 1 micron to about 10 mm, but with no particular limitations, with a spherical or elongated shape (Column 5, lines 35-44 and column 6, lines 1-3 and 29-31). The Examiner interprets this to read upon beads. Hirai et al. disclose a silver particle-polystyrene resin composite bearing  $81 \times 10^{-7}$  mole (as silver atoms) per gram of the polystyrene resin (Column 18, lines 5-9). The Examiner calculates this to represent about 0.87 mg of silver per gram of resin. The resin was

made by adding a silver particle dispersion consisting of silver nitrate and poly(N-vinyl-2-pyrrolidone) to a macroporous polystyrene resin (For Applicant's benefit, the Examiner has attached the product information sheet for Bio-Beads SM-2 from Bio-Rad Laboratories.) and thereby adsorbing the silver particles onto the polystyrene resin (instant claims 1-3, 6, 8, 12 and 13) (Column 17, Example 15). It is the Examiner's position that the macroporous beads would inherently have at least a portion of the silver within the beads and thus read on instant claim 9. Poly(N-vinyl-2-pyrrolidone) acts a physiologically tolerable binding matrix thus anticipating instant claims 24, 25, 28 and 29.

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

With respect to the tissue necrosing amount of a water soluble silver ion releasing compound, the Examiner does not have the capacity to test the composition of Hirai et al. to observe whether or not it will necrose tissue. When the compositions between the prior art and the instantly claimed invention appear to be the same then the burden is placed on the Applicant to demonstrate otherwise.

**Response to arguments:**

Applicant asserted that Hirai et al. do not teach the instantly claimed size limitation in claim 1. The Examiner respectfully disagrees. Hirai et al. disclose a solid carrier that is preferable porous and made from organic polymers such as polystyrene and have a size of from about 1 micron to about 10 mm, but with no particular limitations, with a spherical or elongated shape (Column 5, lines 35-44 and column 6, lines 1-3 and 29-31). It is the Examiner's position that any amount of antibacterial metal located on the surface of the bead would serve to coat the bead to some degree. The intended use of the beads is not further limiting as explained in the prior office action.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsukisaka et al. (JP 05345010A).

The reference of Tsukisaka et al. (Abstract DERWENT-ACC-NO: 1994-039723 JP 05345010A and the machine translation) are discussed in detail above and that discussion is hereby incorporated by reference.

The Tsukisaka et al. do not expressly disclose that the beads are foamed polyethylene, foamed polypropylene or solid polypropylene.



It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use solid or foamed polypropylene or polyethylene as a silver ion delivery vehicle and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because the Abstract states that polyethylene beads and styrene beads can be used. It is deemed merely a matter of judicious selection of known polymeric materials, which is well within the purview of one of ordinary skill in the art. Polypropylene beads are a homolog of polyethylene beads and would be immediately obvious to one of ordinary skill in the art. "Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties." Deuel, 51 F.3d at 1558, 34 USPQ2d at 1214.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teaching of the cited reference.

**Response to arguments:**

Applicant asserted that the disclosure of Tsukisaka et al. provide for a product that is not suitable for the intended purpose of the present invention. The Examiner does not find this persuasive, for the reasons of record and maintains the rejection.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Claims 14-23 and 27 are objected to as being dependent upon a rejected base claim, but would be allowable, pending a search update at time of allowance, if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claims are allowed at this time.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

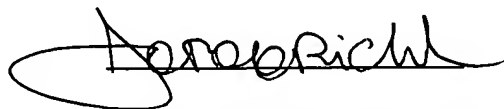
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later

than SIX MONTHS from the mailing date of this final action. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernst Arnold  
Patent Examiner  
Technology Center 1600  
Art Unit 1616

A handwritten signature in black ink, appearing to read 'Johann Richter', with a large, stylized loop at the beginning.

Johann Richter, Ph.D. Esq.  
Supervisory Patent Examiner  
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